Exhibit G

COPY

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May 1, 2009

VIA E-MAIL (sakineh.walther@fda.hhs.gov)
(Original Sent Via Overnight Mail)

Not For Public Disclosure
Contains Confidential
Commercial Information

Ms. Sakineh Walther
Consumer Safety Officer
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
W051 RM5242
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Response to Warning Letter to Cody Laboratories, Inc.

Dear Ms. Walther:

On behalf of Cody Laboratories, Inc. ("Cody"), a wholly-owned subsidiary of the Lannett Company ("Lannett"), we are responding to the above-captioned Warning Letter dated March 30, 2009 issued by Deborah M. Autor, Esq., Director, Office of Compliance. This response is due on May 1, 2009 pursuant to an understanding with the Division of New Drugs and Labeling Compliance (the Division). We also acknowledge and appreciate the opportunity to meet directly with the Agency on April 15, 2009 to discuss the issues raised herein. A copy of our Minutes from the meeting are included in this response as Attachment "A."

I. Background

The Warning Letter contends that Morphine Sulfate Solution Immediate Release 20 mg/ml manufactured by Cody is a "new drug" that has not been reviewed and approved by the U.S. Food and Drug Administration ("FDA"). According to FDA, this drug, therefore, may not be introduced or delivered for introduction into interstate commerce in the absence of an approved new drug application ("NDA") or abbreviated new drug application ("ANDA"). In the absence of such an approval, the Warning Letter also contends that the product fails to bear adequate directions for use and is misbranded.

Please note that the morphine product is manufactured for the Lannett Company ("Lannett") by Cody. Lannett received a similar Warning Letter requesting that it also discontinue production and marketing of Morphine Sulfate within 60-days. Its response is also due by May 1, 2009. We also represent Lannett in this matter and will be responding separately.

The Warning Letter to Cody is one of nine warning letters issued by FDA at the same time regarding drug products containing Morphine Sulfate, Hydrmorphone, or oxycodone, as part of its "unapproved drugs" initiative set forth in Compliance Policy Guide Section 440.100, Marketed New Drugs Without Approved NDAs or ANDAs ("CPG"), available at http://www.fda.gov/cder/guidance/6911fnl.pdf.

Since the Warning Letters were issued on March 30, 2009, and as Cody had discussed with the Division, FDA discovered that the concentrated Morphine Sulfate solution (20 mg/ml) manufactured and marketed by Lannett and Cody was indispensible in the palliative care community. In order to prevent shortages and hoarding of existing supplies, FDA agreed to modify its announced decision to remove unapproved products from the market utilizing its enforcement discretion. FDA announced that this product can remain on the market until 180 days following the date an approved product, or viable alternative, is available on the market (see http://www.fda.gov/cder/drug/unapproved_drugs/morphine_extension.htm). At FDA's request, Cody has also worked to increase the production and distribution of Morphine Sulfate concentrate solution to meet existing demand making up for production lost when the drugs of KV Pharmaceuticals were removed from the marketplace.

Lannett and Cody continue to work with the Agency to prepare, organize and submit the data FDA needs to insure the continued safe and effective use of these products. These actions are described below. At the same time, in Cody's defense, the following facts need to be presented for the Agency's review and consideration:

(1) Its morphine product is lawfully manufactured and marketed based on its "grandfather" status, and the "new drug" requirements are not applicable.

(2) In any event, as discussed herein, Lannett/Cody expects to be able to submit a Section 505(b)(2) NDA for Morphine Sulfate by December 31, 2009.

(3) Review of the history of this product demonstrates that it fails to meet the CPG trigger points for taking this type of enforcement action demanding that all manufacturing cease immediately, and not later than May 29, 2009 (60 days from the date of the Warning Letter). The Warning Letter should be rescinded or modified, within FDA's enforcement discretion, to permit continued manufacture and marketing as long as an application has been submitted to FDA and accepted for filing by December 31, 2009.

II. Morphine Sulfate Is Not a New Drug

In its CPG, FDA recognizes the possibility that a currently marketed prescription drug is grandfathered or is otherwise not a new drug. Id. at p. 11. As FDA explained in the CPG, there are two grandfather provisions that helped make up the current Food Drug and Cosmetic Act (the Act). Under the 1938 grandfather clause, 21 U.S.C. §321(p)(1), a drug product that was on the market prior to passage of the 1938 Act and which contained in its labeling "the same representations concerning the conditions of its use" as it did prior to passage of that Act was not considered a new drug. It, therefore, remains exempt from the requirement of maintaining an approved new drug application. Under the 1962 grandfather clause, the Act exempts a drug from the effectiveness requirements if its composition and labeling has not changed since 1962 and if, prior to enactment of the 1962 amendments, it was: (a) used or sold commercially in the U.S.; (b) was not a new drug; and (c) was not covered by an effective NDA, *see* CPG at page 10 and Public L. 87-781, section 107, reprinted following 21 U.S.C. §321.

Concededly, both FDA and the few relevant court decisions construed these grandfather provisions narrowly. However, it is important to recognize that the 1962 provision is more restrictive than the 1938 clause. The former calls for a comparison of the drug products' conditions of use, composition and labeling, while the 1938 clause focuses only on a comparison of their conditions of use. Even though the courts, and FDA, have narrowly interpreted grandfather status, the Cody morphine products still fall within even the most narrow interpretations. Morphine was available well before 1938 in Morphine Sulfate form in numerous sizes and configurations and that is well documented.

The distinction between the pre-38 and pre-62 products is also critical in assessing the regulatory status of a very old drug like Morphine Sulfate. Lannett and Cody have maintained and shared historical files regarding the marketing and labeling of the product. Those records, which have been available for inspection by FDA, and have been offered to FDA investigators on numerous occasions, demonstrate that undiluted immediate release Morphine Sulfate solution has been commercially sold and marketed in the United States since at least 1900, well before enactment of the 1938 Act. Its conditions of use (for the relief of severe acute and severe chronic pain) have not changed since that time. Please note, for example, the attached excerpt from the 1936 U.S. Pharmacopoeia (Attachment "B") reflecting that Morphine Sulfate (oral solutions and tablets) were contained on its official list of "Pre-1938" products. During this early period, Morphine Sulfate was normally compounded by pharmacists to order at various strengths based on the needs of the patient (e.g., morphia powder, distilled water and diluted sulphuric acid). The notebook of original historical documents contained in Lannett's offices (which we are happy to copy and send to you at your request) definitively demonstrates that the drug was on the market for the same use. This is the extent of Cody's burden of proof under 21 U.S.C. §321(p)(1). Accordingly, Cody's Morphine Sulfate is not a new drug and may be lawfully manufactured and marketed in the absence of an approved application.

Despite our legal opinion to Cody that its Morphine Sulfate solution is one of only a very few current drugs legally grandfathered under the 1938 Act, Lannett/Cody has opted to prepare a

NDA application under §505(b)(2) of the Act. This action was requested (demanded) by FDA during our meeting on April 15, 2009. Following that meeting, both companies reached out to the CDER Division of Anesthesia, Analgesia, and Rheumatology Products (DAARP) on April 21, 2009 via email to Ms. Parinda Jani as directed. Mr. Ernest Sabo, Lannett Vice President, Regulatory and Corporate Compliance, requested a face-to-face pre-IND meeting to discuss the elements of the application. A follow-up letter was provided fulfilling the regulatory requirements of a Pre-IND Review Request. Six-months of accelerated stability data and a preservative study were included in the request letter. On April 29, 2009, Ms. Jani responded that she was "setting up a teleconference with Lannett and Cody in June." Certainly, given the extreme time limitations created by FDA in the exercise of its enforcement discretion (which could be as short as 6 months), it is the responsibility of the review division to prioritize this process. That does not appear to be happening.

It is only rational and reasonable under these circumstances that FDA would permit a product, for which safety or efficacy have not been questioned, to remain on the market if a complete application has been received by FDA and accepted for filing prior to the enforcement deadline. This is especially true if, as you stated on April 15, 2009, the purpose of issuing the Warning Letters was to obtain data from the manufacturer, and not to remove existing drugs from the market where a shortage already exists. Cody cannot control the pace of FDA application review, and FDA likely does not want to create additional pressure on its review staff. Therefore, Cody requests FDA to exercise its enforcement discretion to maintain its Morphine Sulfate solution (20 mg/ml) on the market as long as a complete §505(b)(2) NDA is provided to the Agency no later than December 31, 2009 (180 days from the date of the likely first approval). Lannett/Cody will try to complete the application as expeditiously as possible before that date.

III. FDA Should Defer Enforcement Action

The stated purpose of the CPG was to describe how FDA intended to exercise its enforcement discretion with regard to prescription (Rx) drugs marketed in the US that do not have FDA marketing approval. Concededly, FDA maintains discretionary latitude concerning how it exercises it enforcement discretion in such matters (although not unlimited discretion since its decisions cannot be arbitrary, capricious or abuse the Agency's discretion). Nonetheless, Cody respectfully contends that enforcement action should be deferred with respect to its Morphine Sulfate Rx drug product.

The CPG employs a risk-based approach. It delineates six categories of drugs to which it will accord "higher priority to enforcement actions involving unapproved drug products." CPG at pp. 3-4. Understandably, the top two categories are drugs with potential safety risks and "drugs that lack evidence of effectiveness." There are no issues regarding Morphine Sulfate with regard to either adverse events or concerns that the drug is not effective. Neither Lannett nor Cody are aware of any adverse events or adverse event reports. Medical students and nurses are trained routinely in the use and effects of morphine. Cody follows all applicable GMPs, further lowering any risks. Similarly, category nos. 3, 4, and 6 do not apply.

That leaves category no. 5 "unapproved new drugs that are also violative of the Act in other ways." However, this category is really intended to signal that when FDA has other concerns about an unapproved drug—such cGMP violations—it may extend enforcement action to include unapproved new drug charges. Here, there have been no such "other concerns."

Finally, the CPG contains another section—"Special Circumstances—Newly Approved Product"—indicating that the Agency is more likely to initiate enforcement action when a product in an unapproved class of products has received approval. Id. at pp. 5-6. With regard to Morphine Sulfate, Roxane received approval of its §505(b)(2) NDA in March 2008. Lannett/Cody has begun work on its own application. However, there are drug product differences (e.g., Roxane's drug is diluted at 10 and 20 mg/5 ml v. Cody's concentrated solution at 20 mg/1ml). Cody will need some guidance concerning the data expected in an application. During our April 15 meeting, FDA indicated that the appropriate regulatory pathway is a §505(b)(2) NDA, consisting primarily of CMC information, and that the reviewing division would help advise Lannett and Cody throughout this process.

IV. More Flexible Approach

FDA acknowledges that it maintains the discretion to afford as much or as little of a grace period as it desires on a case-by-case basis. CPG at page 6. The CPG, likewise, identifies factors to be considered in assessing the grace period to allow. Id. None of the factors support the strict and inflexible approach contained in Warning Letters to seven companies issued on March 30, 2009 (and subsequent press releases). In fact, the first factor, whether the product is medically necessary, has now been recognized by FDA as necessitating a different approach for Morphine Sulfate immediate release concentrated solution: allowing up to 180 days following the first approval of this dosage form instead of 60 and 90 days respectively, for the manufacturing and shipment of product to cease. *See* April 9, 2009 FDA letter (Attachment "C"). This approach is reportedly in recognition of drug shortages and the critical need to maintain availability of this product by desperately and terminally ill patients in palliative care who cannot swallow tablets, maintain sufficient IV flow (or endue the pain of continuous injection), or swallow sufficient liquids. In any event, Lannett/Cody and FDA resources, expected for the preparation and review of the Morphine Sulfate 505(b)(2) application, all support flexibility and additional enforcement discretion.

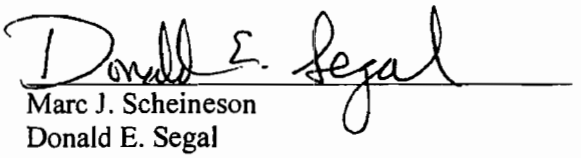
FDA initiatives against other unapproved drugs likewise support more leniency and flexibility with regard to Morphine Sulfate. For example, for levothyroxine and digoxin, FDA negotiated timeframes with product manufacturers and FDA sought to persuade companies to submit NDA/ANDAs in a timely manner so as not to disrupt existing product supply. FDA extended the timeframe for application submission to a total of 3 years despite safety concerns regarding drug potency and stability.

V. Conclusion

Cody appreciates the opportunity collaborate with FDA, including the opportunity to meet on April 15, 2009. The Company continues to cooperate fully with the agency and is committed to meet FDA objectives in a timely manner while doing its part to avoid market shortages. It is also good public policy for the FDA to interact and compromise with cooperating companies in this context to address differences of opinion and legitimate concerns. In this regard, Cody respectfully requests that FDA permit immediate-release Morphine Sulfate solution (20 mg/ml) to remain on the market if a §505(b)(2) NDA is prepared and accepted for filing by FDA prior to December 31, 2009.

Thank you for your consideration of the information and issues raised herein. Please contact either of us with any questions, comments or if we may be of further assistance.

Sincerely,



Marc J. Scheineson
Donald E. Segal
Counsel to Cody Labs

enclosures

cc: Richard Asherman, CEO
Barry Sugarman, Co-CEO
Deborah M. Autor, Esq.
Donna Katz, Esq.
Ms. Jennifer Devine
Mr. Gary Buehler
Mr. Howard Manresa
Mr. Thomas Gardine

Attachment "A"

Brief Summary of Lannett/Cody Meeting with FDA on April 15, 2009

Attendees:

For Lannett/Cody:

- Arthur Bedrosian, President/CEO Lannett
- Ernest Sabo, VP-Regulatory Compliance- Lannett
- Robin Dornewass, Director-Quality Assurance- Lannett
- Barry Sugarman,* Co-CEO- Cody Laboratories
- Marc Scheineson, Regulatory Counsel, Alston + Bird
- Donald Segal, Regulatory Counsel, Alston + Bird

For FDA:

- Deborah Autor, Director, FDA/CDER/Office of Compliance (OC)
- Jennifer Devine, Associate Director, FDA/CDER/OC/Division of New Drugs and Labeling Compliance (DNDLC)
- Judy McMeekin, Team Leader, FDA/CDER/OC/DNDLC/New Drugs and Labeling Team (NDLT)
- Sakineh Walther, Compliance Officer, FDA/CDER/OC/DNDLC/NDLT
- Steven Lynn, Project Management Officer, FDA/CDER/OC
- Donna Katz, Attorney, FDA/Office of Chief Counsel
- Jouhayna Saliba, Senior Program Management Officer, CDER/Office of New Drugs (OND)/Drug Shortage Staff (DS)
- Andrei Nabakowski, Senior Program Management Officer, CDER/OND/DS
- David Read, Regulatory Counsel, CDER/Office of Generic Drugs
- Paul Teitell, CSO, ORA/ Denver District*
- Elvin Smith, Supervisory CSO, ORA/DEN-DO*
- Ricki Chase, Supervisory CSO, ORA/DEN-DO*
- Howard Manresa, Supervisory CSO, ORA/DEN-DO*
- Nancy Schmidt, CSO, ORA/DEN-DO*
- Steven Carter, Supervisory CSO, ORA/Philadelphia-District*
- Sharon Hertz, Supervisory Medical Officer, CDER/OND/Office of Drug Evaluation II/ Division of Anesthesia, Analgesia and Rheumatology Products*

* By Telephone

The meeting lasted a little more than one hour, beginning with introductions. Without attempting to capture the back-and-forth dialogue, below is a brief summary of the topics and "decisions" reached.

A. Morphine Sulfate

- By letters dated April 9, 2009, FDA extended the period of enforcement discretion with regard to morphine sulfate oral solution 20mg/ml products, until 180 days after any firm receives approval for such a product or if FDA determines that alternative medications become available for the palliative case of patients. During the meeting, FDA (Autor) stated that:

  (a) The 180-day period would not be extended;
  (b) The agency would not say whether an application had been filed or, if so, who filed it.

- Grandfather – Lannett stated that it maintains a historical file and very few, if any, other companies likely do so. FDA did not respond specifically, other than to restate its general skepticism with regard to grandfather status.

- The regulatory pathway recommended by FDA is the 505(b)(2) application. This would likely mimic the recent Roxane approvals (primarily CMC and pharmacokinetic data). An ANDA is not recommended, and this also avoids the necessity for a suitability petition. Lannett is encouraged to contact the Division to discuss an IND.

- If the 505(b)(2) application provides information to support further need for the product to address a new shortage, FDA would strongly consider priority review.

B. Hydromorphone

- FDA (D. Read) acknowledged that there are no remaining issues with respect to the ANDAs (2/4/8 mg.) except for Cody inspectional issues.

- FDA (Denver) does not dispute that Cody essentially "passed" the reinspection in April 2007, but stated that the District needs to review manufacture of API while in production before the inspection is complete. There was some reluctance by Denver to commit to having an inspector at Cody once Cody reports it is in production. However, D. Autor seemed willing to work with the District concerning scheduling the inspection. It

appears that if Cody provides advance notice concerning when it will be in production, the District will either inspect during that time, or inspect the resulting batch records when available.

- The Warning Letters stated that enforcement discretion with regard to Hydromorphone HCl Tablets, 2 mg. and 4 mg., would not be extended beyond 60 days for manufacture, and 90 days for shipment in interstate commerce. FDA did not express a willingness to extend those time frames. However, the history of the ANDAs and Lannett/Cody's active and continuing pursuit of approval may make it more difficult for FDA to take further action under those circumstances.

General observations:

- At no time did FDA raise serious concerns about:

  -The actual safety or effectiveness of either product;
  -GMP compliance of Lannett
  -The good faith of either Lannett or Cody

- The unapproved drugs group seemed, as a general matter, skeptical about the intentions of companies marketing such products. Lannett sought to distinguish itself from those companies evading regulation.

Attachment B

THE

PHARMACOPŒIA

OF THE

UNITED STATES OF AMERICA

ELEVENTH DECENNIAL REVISION
(U. S. P. XI)

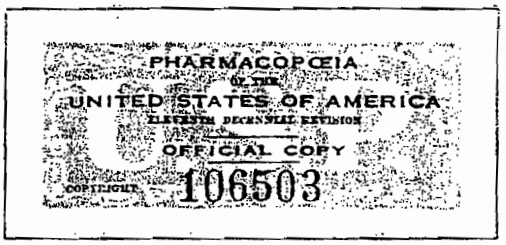
BY AUTHORITY OF THE
UNITED STATES PHARMACOPŒIAL CONVENTION
HELD AT WASHINGTON, D. C., MAY 13 AND 14, 1930

PREPARED BY THE COMMITTEE OF REVISION AND
PUBLISHED BY THE BOARD OF TRUSTEES

OFFICIAL FROM JUNE 1, 1936

AGENT

MACK PRINTING COMPANY
EASTON, PA.



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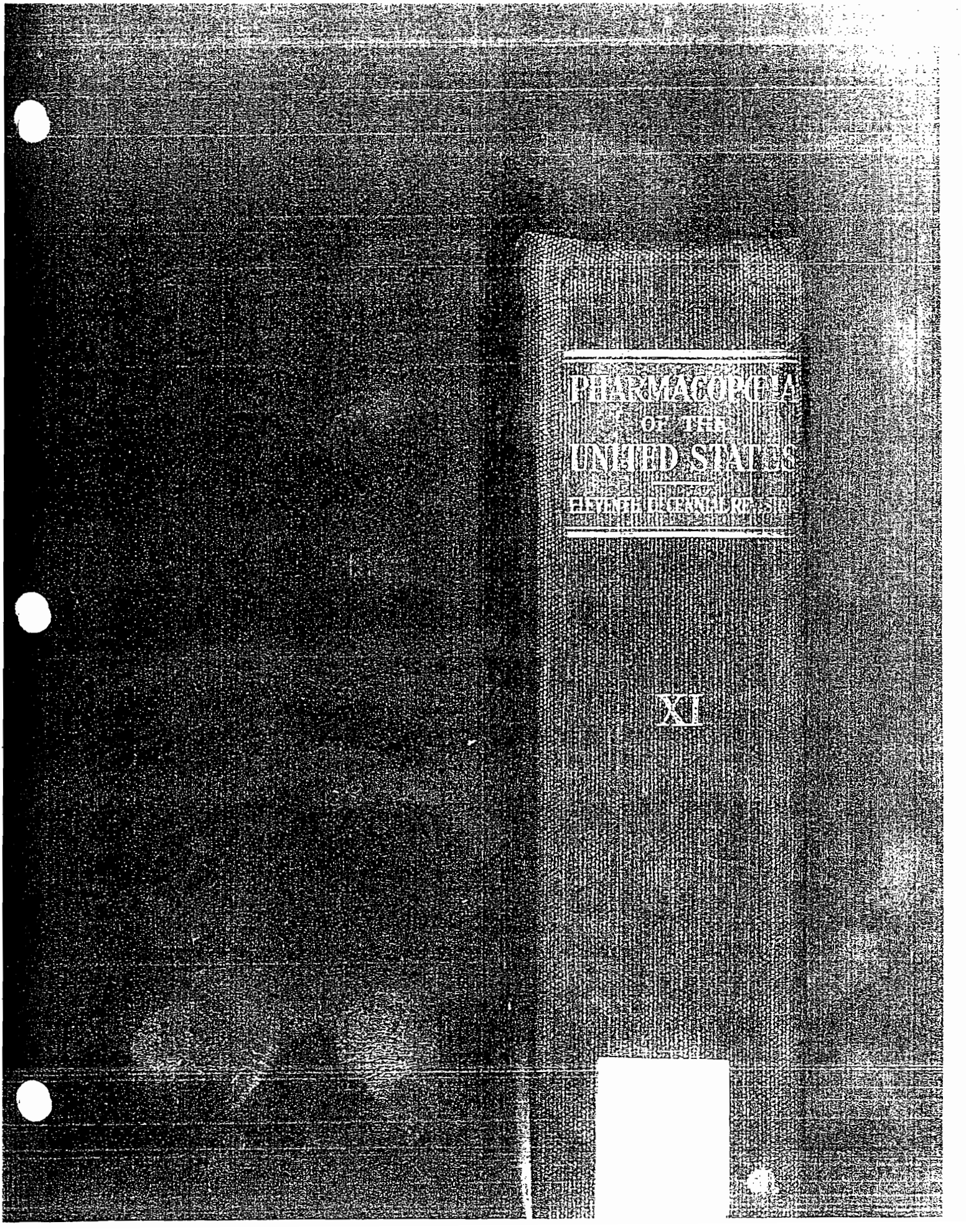
PHARMACOPEIA
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UNITED STATES
ELEVENTH DECENNIAL REVISION
XI

keeping the mixture in constant rotation. Stopper the flask and allow the mixture to stand for fifty minutes, shaking it vigorously at intervals of ten minutes. Add distilled water to make the mixture measure 500 cc., mix thoroughly, allow to stand for ten minutes, and filter through a filter that has not been previously moistened. Reject the first 30 cc. of filtrate. Determine the excess of iodine by titration of 100 cc. of the subsequent filtrate with tenth-normal sodium thiosulfate. Each cc. of tenth-normal iodine is equivalent to 0.005328 Gm. of $C_{16}H_{18}N_2ClS$.

Storage—Preserve Methylthionine Chloride in well-closed containers.

AVERAGE DOSE—Metric, 0.15 Gm.—Apothecaries, 2½ grains.

MISTURA CRETÆ

Chalk Mixture

Mist. Cret.

COMPOUND CHALK POWDER	20 Gm.
CINNAMON WATER	40 cc.
DISTILLED WATER, a sufficient quantity,	
To make	100 cc.

Gradually add the cinnamon water and about 20 cc. of distilled water to the compound chalk powder in a mortar, triturating until the mixture is uniform; transfer this to a graduated vessel, rinse the mortar with enough distilled water to make the product measure 100 cc., and mix thoroughly.

Caution—This preparation must not be dispensed unless it has been recently prepared.

AVERAGE DOSE—Metric, 15 cc.—Apothecaries, 4 fluidrachms.

MISTURA OPII ET GLYCYRRHIZÆ COMPOSITA

Compound Mixture of Opium and Glycyrrhiza

Mist. Opii et Glycyrrh. Comp.—Mistura Glycyrrhizæ Composita U. S. P. X, Compound Mixture of Glycyrrhiza, Brown Mixture

FLUIDEXTRACT OF GLYCYRRHIZA	120	cc.
ANTIMONY AND POTASSIUM TARTRATE	0.24	Gm.
CAMPHORATED TINCTURE OF OPIUM	120	cc.
SPIRIT OF ETHYL NITRITE	30	cc.
GLYCERIN	120	cc.
DISTILLED WATER, a sufficient quantity,		
To make	1000	cc.

Dilute the fluidextract with the glycerin and 500 cc. of distilled water; add the antimony and potassium tartrate dissolved in 12 cc. of hot distilled water, then add the other ingredients, and enough distilled water to make the product measure 1000 cc.

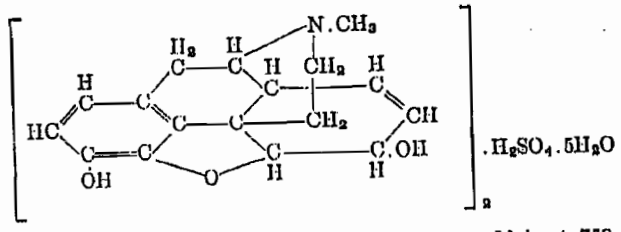
Alcohol content—From 9 to 11 per cent, by volume, of C_2H_5OH.

AVERAGE DOSE—Metric, 4 cc.—Apothecaries, 1 fluidrachm.

MORPHINÆ SULFAS

Morphine Sulfate

Morph. Sulf.



$(C_{17}H_{19}O_3N)_2 \cdot H_2SO_4 \cdot 5H_2O$ Mol. wt. 758.47

The sulfate of the alkaloid morphine.

Description and physical properties—White, feathery, silky crystals, or cubical masses of crystals, or a white, crystalline powder. It is odorless, and is stable in the air.

One Gm. of Morphine Sulfate is soluble in 15.5 cc. of water and in 505 cc. of alcohol, at 25° C. One Gm. is soluble in 0.7 cc. of water at 80° C. and in 240 cc. of alcohol at 60° C. It is insoluble in chloroform and in ether.

Tests for identity—Add a few drops of ammonia T.S. to 5 cc. of an aqueous solution of Morphine Sulfate (1 in 30), and gently shake the mixture: a white precipitate is formed, which dissolves upon the subsequent addition of a few cc. of sodium hydroxide T.S.

Sulfuric acid containing 0.005 Gm. of selenous acid in each cc. gives with Morphine Sulfate a blue color, changing to green and then to brown. (*Codeine* yields a green color, changing to blue and afterward to grass-green.)

Sulfuric acid containing 0.005 Gm. of molybdic acid in each cc. gives with Morphine Sulfate a purple color, changing to blue.

Sulfuric acid containing in each cc. one drop of formaldehyde T.S. yields an intensely purple color with Morphine Sulfate.

With nitric acid Morphine Sulfate produces an orange-red color, fading to yellow.

The addition of a few drops of freshly prepared ferric chloride T.S. to an aqueous solution of Morphine Sulfate (1 in 100) produces a blue color, which is destroyed by acids, by alcohol, or by heating.

Add potassium ferricyanide T.S., containing 1 drop of ferric chloride T.S. in each cc., to an aqueous solution of Morphine Sulfate (1 in 100): a deep blue color is produced at once (difference from *codeine*).

Barium chloride T.S. produces in an aqueous solution of Morphine Sulfate a white precipitate, insoluble in hydrochloric acid.

Tests for purity—The ash from 0.5 Gm. of Morphine Sulfate is negligible, page 439.

A solution of 0.5 Gm. of Morphine Sulfate in 15 cc. of distilled water requires not more than 0.5 cc. of fiftieth-normal sodium hydroxide for neutralization, using 1 drop of methyl red T.S. as the indicator.

Dried to constant weight at 130° C., Morphine Sulfate loses not more than 12 per cent of its weight (*water*).

Warm 0.2 Gm. of Morphine Sulfate with 5 cc. of sodium hydroxide T.S.: the mixture does not evolve a noticeable odor of ammonia (*ammonium salt*).

Add a few drops of ferric chloride T.S. to 5 cc. of an aqueous solution of Morphine Sulfate (1 in 30), previously mixed with 5 cc. of diluted hydrochloric acid: no red color is produced (*meconate*).

Dissolve 1 Gm. of Morphine Sulfate in 10 cc. of sodium hydroxide T.S. in a separator, and shake the solution with three successive portions of 15, 10, and 10 cc. of chloroform, passing the chloroformic solutions through a small filter previously moistened with chloroform. Shake the combined chloroformic solutions with 5 cc. of distilled water, separate the chloroform, and evaporate it carefully to dryness on a water bath. Add to the residue thus obtained 10 cc. of fiftieth-normal sulfuric acid, heat gently until dissolved, cool, add 2 drops of methyl red T.S., and titrate the excess of acid with fiftieth-normal sodium hydroxide: not less than 7.5 cc. of the sodium hydroxide solution is required (*foreign alkaloids*).

Storage—Preserve Morphine Sulfate in well-closed containers, and protected from light.

AVERAGE DOSE—Metric, 0.008 Gm.—Apothecaries, ⅛ grain.

MUCILAGO ACACIÆ

Mucilage of Acacia

Mucil. Acac.—Mucilage of Gum Arabic

ACACIA, in small fragments	350 Gm.
SODIUM BENZOATE	1 Gm.
DISTILLED WATER, a sufficient quantity,	
To make	1000 cc.

Place the acacia in a graduated bottle having a wide mouth and a capacity not exceeding 1000 cc., wash the drug with cold distilled water, allow it to drain, and add enough warm distilled water, in which the sodium benzoate has been dissolved, to make the product measure 1000 cc. After stoppering, lay the bottle on its side, rotating it occasionally, and when the acacia has dissolved, strain the mucilage.

Mucilage of Acacia may also be prepared by adding 400 cc. of distilled water to 350 Gm. of powdered or granular acacia, in a mortar, and triturating until the acacia is dissolved. Then add the sodium benzoate, dissolved in 100 cc. of distilled water, and sufficient distilled water to make the product measure 1000 cc.

Caution—Mucilage of Acacia must not be dispensed if it has become sour or mouldy.

AVERAGE DOSE—Metric, 15 cc.—Apothecaries, 4 fluidrachms.

MUCILAGO TRAGACANTHÆ

Mucilage of Tragacanth

Mucil. Trag.

TRAGACANTH	6 Gm.
GLYCERIN	18 Gm.
DISTILLED WATER, a sufficient quantity,	
To make	100 Gm.

Mix the glycerin with 75 cc. of distilled water in a tared vessel, hea the mixture to boiling, discontinue the application of heat, add th tragacanth, and macerate the mixture during twenty-four hours, stir ring occasionally. Then add enough distilled water to make the mix ture weigh 100 Gm., stir actively until of uniform consistence, an strain forcibly through muslin.

MYRISTICA

Myristica

Myrist.—Nutmeg

Myristica is the dried ripe seed of *Myristica fragrans* Houttuy (Fam. *Myristicaceæ*), deprived of its seed-coat and arillode and wi or without a thin coating of lime.

Myristica yields not less than 25 per cent of non-volatile, ethe soluble extractive, page 475, and not more than 0.5 per cent of aci insoluble ash, page 473.

Description and physical properties—

Unground Myristica—Ovoid or ellipsoidal, from 20 to 30 mm. in length and abo 20 mm. in thickness; externally light brown to dark brown; reticulat furrowed, the broad end with a large, circular, upraised scar from which ari a groove extending to a depression at the opposite end; the cut surface hav a waxy luster and a mottled-brown appearance; odor characteristically a matic; taste pungently aromatic.

Structure—Perisperm thin, dark brown, penetrating by many wavy branches folds into the yellowish-brown endosperm; embryo small and more or shrunken, in an irregular cavity near the base.

Powdered Myristica—Dark reddish-brown; consisting of irregular yellow brown and blackish-brown fragments; perisperm with large, circular elliptical volatile-oil reservoirs, small thin-walled parenchyma cells w brown contents and occasional spiral tracheæ; endosperm with more or polygonal parenchyma cells containing starch and aleurone grains and o sionally brown pigment; fixed oil globules numerous; starch grains singl 2- to 3-compound, or in aggregates, the individual grains, spherical, pl convex or polygonal, from 0.003 to 0.022 mm. in diameter, with a disti sometimes cleft hilum.

Section III

LISTING OF "PRE-1938" PRODUCTS

The Federal Food, Drug, and Cosmetic Act of 1938 required that drugs be shown to meet certain safety requirements prior to their being marketed. Drugs that were already being marketed at that time were "grandfathered" and were allowed to remain on the market without further regulatory approval if they were labeled with the same conditions of use. Many of these products remain on the market today. Because these products technically have never been *approved* by FDA, they do not appear in the listing of approved drug products with therapeutic equivalence evaluations (the "Orange Book").

The following listing identifies drug products that we believe are considered "pre-1938" or "grandfathered" and are still currently available. The list was developed by comparing an earlier general listing of frequently prescribed "pre-1938" drug entities developed by the U. S. Food and Drug Administration against current dosage form listings in the "Orange Book." The listing is not necessarily complete and comments are welcomed. Additions to or deletions from this list will be shown in future issues of *Update*. The listing of these products should not be interpreted as an attestation by USP as to their actual availability or the general recognition of safety and efficacy of the articles for medical or legal purposes or that a final determination has been made by the FDA.

Acetaminophen, Aspirin, Salicylamide, Codeine Phosphate, and Caffeine
  Tablets
Acetaminophen, Codeine Phosphate, and Caffeine
  Capsules
  Tablets
Amobarbital
  Tablets
Amobarbital Sodium
  Capsules
  Sterile
Amyl Nitrate
  Inhalant
Antipyrine and Benzocaine
  Solution, Otic
Aspirin and Codeine Phosphate
  Tablets
Chloral Hydrate
  Capsules
  Syrup
  Suppositories
Codeine and Calcium Iodide
  Syrup
Codeine Phosphate
  Injection
  Solution, Oral
  Tablets
  Tablets, Soluble
Codeine Sulfate
  Tablets
  Tablets, Soluble
Colchicine
  Injection
  Tablets
Digitoxin
  Tablets
Digoxin
  Elixir
  Tablets
Ephedrine Sulfate
  Capsules
  Injection
  Syrup
Ergonovine Maleate
  Injection
  Tablets
Ergotamine Tartrate
  Tablets
Erythrityl Tetranitrate
  Tablets
Hydrocodone Bitartrate
  Tablets
Hydrocodone Bitartrate, Aspirin, and Caffeine
  Tablets
Hydromorphone Hydrochloride
  Suppositories
Iodinated Glycerol
  Elixir
  Solution, Oral
  Tablets
Levothyroxine Sodium
  Injection
  for Injection
  Tablets
Meperidine Hydrochloride and Acetaminophen
  Tablets
Mephobarbital
  Tablets
Methenamine Mandelate
  for Solution, Oral
  Suspension, Oral
  Tablets
  Tablets (Enteric-coated)
Morphine Hydrochloride
  Suppositories
Morphine Sulfate
  Solution, Oral
  Tablets
Nitroglycerin
  Tablets (Sublingual)
Opium Alkaloids Hydrochlorides
  Injection
Opium Tincture
Oxycodone
  Tablets
Oxycodone Hydrochloride
  Solution, Oral
Paregoric
Pentaerythritol Tetranitrate
  Tablets
Phenazopyridine Hydrochloride
  Tablets
Phenobarbital
  Capsules
  Elixir
  Tablets
Phenobarbital Sodium
  Injection
  Sterile
Pilocarpine Hydrochloride
  Solution, Ophthalmic
Pilocarpine Nitrate
  Solution, Ophthalmic
Potassium Bicarbonate
  Effervescent Tablets for Oral Solution
Potassium Bicarbonate and Potassium Chloride
  for Effervescent Oral Solution
  Effervescent Tablets for Oral Solution
Potassium Bicarbonate and Potassium Citrate
  Effervescent Tablets for Oral Solution
Potassium Chloride
  Solution, Oral
Potassium Chloride, Potassium Bicarbonate, and Potassium Citrate
  Effervescent Tablets for Oral Solution
Potassium Gluconate
  Elixir
  Tablets
Potassium Gluconate and Potassium Chloride
  Solution, Oral
  for Solution, Oral
Potassium Gluconate and Potassium Citrate
  Solution, Oral
Potassium Iodide
  Solution, Oral
  Syrup
  Tablets (Enteric-coated)
Monobasic Potassium Phosphate
  Tablets for Oral Solution
Potassium Phosphates
  Capsules for Oral Solution
  for Solution, Oral
Potassium and Sodium Phosphates
  Capsules for Oral Solution
  for Solution, Oral
  Tablets for Oral Solution
Monobasic Potassium and Sodium Phosphates
  Tablets for Oral Solution
Quinacrine Hydrochloride
  Tablets
Quinine
  Capsules
Quinine Sulfate
  Tablets
Salsalate
  Capsules
  Tablets
Secobarbital Sodium and Amobarbital Sodium
  Capsules
Sodium Fluoride
  Solution, Oral
  Tablets
Thyroid
  Tablets
  Tablets, Enteric-coated
Trikates (Potassium Acetate, Potassium Bicarbonate, and Potassium Citrate)
  Solution, Oral

Attachment C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

April 9, 2009

Richard E. Asherman, CEO
Cody Laboratories, Inc.
601 Yellowstone Avenue
Cody, Wyoming 82414

Product:
Morphine Sulfate Solution Immediate Release 20mg/ml

Dear Mr. Asherman:

This letter is written in reference to the March 30, 2009 warning letter (Warning Letter) your firm received for manufacturing morphine sulfate oral solution 20 mg/ml, an unapproved new drug, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

The mission of FDA's Center for Drug Evaluation and Research (CDER) is to assure that safe and effective drugs are available to the American people. The drug approval system is one of the essential means by which CDER achieves its mission and ensures that patients have access to prescription drugs of proven safety, efficacy, and quality.

FDA remains committed to taking enforcement actions against unapproved drugs in an effort to ensure that drugs used by patients are safe and effective, while at the same time ensuring that such actions do not impose an undue burden on patients. Currently, there are no approved morphine sulfate oral solution 20 mg/ml products being marketed in the U.S. FDA has heard from the pain management community that the impending market removal of unapproved morphine sulfate oral solution 20 mg/ml products announced in the Warning Letter would impose extreme hardship on palliative care patients and their families. In light of this information, FDA intends to extend the period of enforcement discretion set forth in the Warning Letter to ensure that palliative care patients have access to morphine sulfate oral solution 20 mg/ml.

The period of enforcement discretion set forth in the Warning Letter will be extended until 180 days after any firm receives approval for a morphine sulfate oral solution 20 mg/ml product. If your firm manufacturers an unapproved morphine sulfate oral solution 20 mg/ml beyond the date that is 180 days after the date of such an approval, that activity may result in legal action without

further notice, including, without limitation, seizure and injunction. The extension of this period of enforcement discretion will not apply if FDA determines that your firm is violating other provisions of the Act or identifies additional safety information, or if FDA determines that alternative medications become available that could meet the needs of palliative care patients. FDA is actively evaluating alternatives to morphine sulfate oral solution 20 mg/ml and working with firms to expedite approval of such products. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations. Please be advised that we are not extending the period of enforcement discretion for any other products identified in the Warning Letter; the period of enforcement discretion stated in the Warning Letter will continue to apply to those other products.

Furthermore, FDA reiterates its expectation that all firms that market unapproved drugs to the American public submit the required applications to obtain approval for those products. FDA intends to continue to take aggressive enforcement action against marketed unapproved drugs.

FDA understands the need to continue to provide assistance to firms and to help them secure approval for unapproved drugs they are currently marketing. As part of this commitment, FDA appointed an unapproved drugs coordinator in the Office of New Drugs, Dr. Sally Loewke, to work with companies trying to bring their products into compliance. Please contact Parinda Jani, Chief Project Manager, Office of New Drugs, at 301-796-1232, about obtaining the necessary approval for your unapproved morphine sulfate oral solution 20 mg/ml drug product or any other unapproved product you may be marketing.

FDA is committed to making sure that patients have access to drugs of proven safety, efficacy, and quality and hopes that your firm shares this same commitment. If you have any additional questions concerning this letter, please contact Ms. Sakineh Walther, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, HFD-310, WO51 RM 542, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

Sincerely,

Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Exhibit H

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993-0002

May 29, 2009

VIA FACSIMILE AND FEDEX

Donald E. Segal, Esquire
Counsel to Lannett Company, Inc.
Alston & Bird LLP
The Atlantic Building
950 F Street NW
Washington DC 20004-1404

Dear Mr. Segal:

This is in reference to your response letter of May 1, 2009, to the Food and Drug Administration (FDA or Agency) Warning Letter issued on March 30, 2009 and FDA's follow-up letter dated April 9, 2009 to your client, Lannett Company, Inc., regarding distribution of unapproved hydromorphone 2 mg and 4 mg tablets and morphine sulfate oral solution 20 mg/ml drug products. Your response to the Warning Letter is not adequate.

You have asserted that your client's drug products are grandfathered. FDA is aware that some firms market products that they claim are "grandfathered" under the 1938 Act or the 1962 Amendments to the Act, as defined by section 201(p)(1) of the Act [21 U.S.C. § 321(p)(1)] and Section 107(c)(4) of the 1962 Amendments. The grandfather clauses in the Act have been construed very narrowly by the courts (see the appendix of our marketed unapproved drugs CPG, http://www.fda.gov/cder/guidance/6911fnl.htm, lines 323-329). Companies claiming that their products are grandfathered are responsible for fully documenting their products' grandfathered status. As we discussed in our meeting of April 15, 2009, if your client wishes to pursue its assertion that its products are grandfathered, it must provide documentation to Deborah Autor, including but not limited to pre-1938 or pre-1962 labeling, to demonstrate that the products meet all the criteria for grandfather status, including that the products as marketed today have the same formulations, strengths, dosage forms, routes of administration, indications, intended patient populations, and other conditions of use as the pre-1938 or pre-1962 products. For further information please refer to 21 CFR 314.200(e).

We disagree with your assertion that your products "fail to meet the CPG trigger points for taking this type of enforcement action." We note that your client's products that are subject to the Warning Letter are priorities under several of the priorities set forth in the Agency's guidance entitled "Marketed Unapproved Drugs - Compliance Policy Guide" (CPG). Further, the CPG explicitly states that it provides notice that any product being marketed illegally is subject to FDA enforcement action at any time. Therefore, your client has no basis to claim that the Agency must defer action on its illegally marketed

products to a later time. Please be advised that if your client distributes these unapproved products beyond the periods of enforcement discretion set forth in the March 30, 2009 Warning Letter and the follow-up letter dated April 9, 2009, that activity may result in legal action without further notice, including, without limitation, seizure and injunction. In addition, please note that if FDA finds it necessary to take enforcement action against a product covered by the Warning Letter, the agency may take action relating to all of your client's other violations of the Federal Food, Drug, and Cosmetic Act (the Act) at the same time. For example, if your client continues to distribute a product covered by the Warning Letter after the applicable enforcement date has passed, FDA may take enforcement action relating to all of your client's unapproved drugs that require applications at the same time (see, e.g., *United States v. Sage Pharmaceuticals*, 210 F.3d 475, 479-80 (5th Cir. 2000) (permitting the agency to combine all violations of the Act in one proceeding, rather than taking action against multiple violations of the Act in "piecemeal fashion")).

Sincerely,

Michael M. Levy, Jr., Esq.
Director
Division of New Drugs and Labeling
Office of Compliance
Center for Drug Evaluation and Research

cc: Arthur P. Bedrosian
Deborah Autor
Gary Buehler
Donna Katz
Jennifer Devine
Sakineh Walther
Thomas Gardine
David Read
Sharon Hertz

Exhibit I

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993-0002

May 29, 2009

VIA FACSIMILE AND FEDEX

Donald E. Segal, Esquire
Counsel to Cody Laboratories, Inc.
Alston & Bird LLP
The Atlantic Building
950 F Street NW
Washington DC 20004-1404

Dear Mr. Segal:

This is in reference to your response letter of May 1, 2009, to the Food and Drug Administration (FDA or Agency) Warning Letter issued on March 30, 2009 and FDA's follow-up letter dated April 9, 2009 to your client, Cody Laboratories, Inc., regarding manufacturing and distribution of unapproved hydromorphone 2 mg and 4 mg tablets and morphine sulfate oral solution 20 mg/ml drug products. Your response to the Warning Letter is not adequate.

You have asserted that your client's drug products are grandfathered. FDA is aware that some firms market products that they claim are "grandfathered" under the 1938 Act or the 1962 Amendments to the Act, as defined by section 201(p)(1) of the Act [21 U.S.C. § 321(p)(1)] and Section 107(c)(4) of the 1962 Amendments. The grandfather clauses in the Act have been construed very narrowly by the courts (see the appendix of our marketed unapproved drugs CPG, http://www.fda.gov/cder/guidance/6911fnl.htm, lines 323-329). Companies claiming that their products are grandfathered are responsible for fully documenting their products' grandfathered status. As we discussed in our meeting of April 15, 2009, if your client wishes to pursue its assertion that its products are grandfathered, it must provide documentation to Deborah Autor, including but not limited to pre-1938 or pre-1962 labeling, to demonstrate that the products meet all the criteria for grandfather status, including that the products as marketed today have the same formulations, strengths, dosage forms, routes of administration, indications, intended patient populations, and other conditions of use as the pre-1938 or pre-1962 products. For further information please refer to 21 CFR 314.200(e).

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products to a later time. Please be advised that if your client distributes these unapproved products beyond the periods of enforcement discretion set forth in the March 30, 2009 Warning Letter and the follow-up letter dated April 9, 2009, that activity may result in legal action without further notice, including, without limitation, seizure and injunction. In addition, please note that if FDA finds it necessary to take enforcement action against a product covered by the Warning Letter, the agency may take action relating to all of your client's other violations of the Federal Food, Drug, and Cosmetic Act (the Act) at the same time. For example, if your client continues to distribute a product covered by the Warning Letter after the applicable enforcement date has passed, FDA may take enforcement action relating to all of your client's unapproved drugs that require applications at the same time (see, e.g., *United States v. Sage Pharmaceuticals*, 210 F.3d 475, 479-80 (5th Cir. 2000) (permitting the agency to combine all violations of the Act in one proceeding, rather than taking action against multiple violations of the Act in "piecemeal fashion")).

Sincerely,

Michael M. Levy, Jr., Esq.
Director
Division of New Drugs and Labeling
Office of Compliance
Center for Drug Evaluation and Research

cc: Richard E. Asherman
Deborah Autor
Gary Buehler
Donna Katz
Jennifer Devine
Sakineh Walther
Howard Manresa
David Read
Sharon Hertz

Exhibit J

News & Events

FDA NEWS RELEASE

For Immediate Release: Jan. 26, 2010
Media Inquiries: Christopher Kelly, 301-796-4676, christopher.kelly@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Approves Morphine Sulfate Oral Solution for Relief of Acute and Chronic Pain

Approval is part of Agency's unapproved drugs initiative

The U.S. Food and Drug Administration approved Morphine Sulfate Oral Solution for the relief of moderate to severe, acute and chronic pain in opioid-tolerant patients. This medicine will be available in 100 milligrams per 5 mL or 20 milligrams per 1 mL.

This is the only FDA approved morphine sulfate oral solution available at this concentration. Although the use of this medicine to manage pain has been common practice for many years, this form and concentration of morphine was not FDA approved until now.

Today's action is part of the FDA's unapproved drugs initiative. As part of this program, the FDA has worked with the manufacturer of the now-approved product, Roxane Laboratories, to ensure that there is enough drug available for patients. The FDA will also be working with patient organizations and prescribers so that they are aware that an approved product is available, and can notify the FDA if there are any problems with availability.

"An important goal of the unapproved drugs initiative is to make sure that marketed drugs meet current FDA standards," said Douglas Throckmorton, M.D., deputy director for the FDA's Center for Drug Evaluation and Research. "Our action today reflects a careful balance between ensuring patient access to necessary medicines, while making sure companies comply with the law."

One benefit of the FDA approval process is a requirement for manufacturers to provide sufficient information on how to safely prescribe and use a drug. Manufacturers may also have to establish additional safety measures to manage unique risks of a medicine. For this formulation of morphine, the manufacturer had to develop a safety program prior to approval to address the known risks of morphine misuse, abuse and overdose.

For more information:

March 31, 2009 Warning Letters, companies, and affected products
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm118712.htm[1]

List of FDA-approved drug products
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm[2]

#

Note: This press release was amended because the action took place on January 25, 2010.

RSS Feed for FDA News Releases[3] [what is RSS?[4]]

Links on this page:

1. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm118712.htm
2. http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm
3. http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/PressReleases/rss.xml
4. http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/ucm144575.htm

Exhibit K

"The Pink Sheet" Daily
January 26 2010

Roxane's Oral Morphine Sulfate Gets FDA Approval, But Also Inventory Oversight

FDA is taking an unusually active role in helping a manufacturer ensure the supply of one of its own products - Roxane Laboratories' Morphine Sulfate Oral Solution, approved Jan. 26.

"Through its Drug Shortage Program, the FDA will closely monitor the inventory and sales data to availability of the product and provide a 1-800 number to pharmacies and health care providers, enabling them to order it directly from the manufacturer in the event there is any difficulty obtaining the product through the normal channels from their wholesalers or distributors," FDA said.

The concern stems from the fact that Roxane's product is now the only approved one on the market, and FDA expects all the demand to shift its way.

Roxane, a subsidiary of Boehringer Ingelheim, said there is nothing to worry about, since "we have a sufficient supply today to meet the entire market supply, and we don't anticipate any shortage because we are manufacturing constantly and can meet demand as it comes in."

The approval helps solve a problem that came to a head in March 2009, when FDA told seven manufacturers and distributors of high-concentration oral morphine sulfate, none of which were approved drugs, to cease their operations. The following month FDA reversed course, allowing them to continue production in an effort to avoid a shortage of the medically necessary opioid product ('The Pink Sheet' DAILY, April 10, 2009).

Now that it has approved Roxane's product, FDA is putting on the red light for competitors, requiring them to submit an NDA or withdraw their comparable unapproved morphine sulfate products from the market. How aggressive the agency becomes in that effort will likely depend on how confident it is in Roxane's ability to supply the market.

The approval of Roxane's Morphine Sulfate Oral Solution is part of FDA's Unapproved Drugs Initiative, which began in 2006, CDER Deputy Director Douglas Throckmorton, noted in a media conference call Jan. 26. Through the initiative, the agency seeks to "balance the need for older, unapproved drugs," a category in which many morphine products fall, "with the need for quality drugs," he said.

Roxane's morphine sulfate will be available in 100 mg/5 mL and 20 mg/1 mL strengths, making it the only FDA-approved morphine sulfate oral solution available at this concentration.

"An important goal of the unapproved drugs initiative is to make sure that marketed drugs meet current FDA standards," Throckmorton said.

The company will be feeling little pain from the Risk Evaluation and Mitigation Strategy FDA is imposing as a condition of approval; the REMS is solely a Medication Guide.

-Martin Berman-Gorvine (m.berman-gorvine@elsevier.com)

Exhibit L

U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Drugs

Resolved Drug Shortages

Drug Name	Company Information	Related Information
Acyclovir Tablets and Capsules	Teva Pharmaceuticals 1-800-545-8800	Teva is releasing acyclovir tablets as they become available.
7/2/2010	GlaxoSmithKline 1-888-825-5249	GlaxoSmithKline has Zovirax 200mg, 400mg, and 800 mg tablets available.
	Mylan Pharmaceuticals 1-800-796-9526	Mylan reports the following available presentations: Acyclovir Capsules USP, 200 mg, Bottles of 100, NDC 0378-2200-01 Acyclovir Capsules USP, 200 mg, Bottles of 500, NDC 0378-2200-05 Acyclovir Tablets USP, 400 mg, Bottles of 100, NDC 0378-0253-01 Acyclovir Tablets USP, 400 mg, Bottles of 500, NDC 0378-0253-05 Acyclovir Tablets USP, 800 mg, Bottles of 100 NDC 0378-0302-01 Acyclovir Tablets USP, 800 mg, Bottles of 500, NDC 0378-0302-05
	Carlsbad Technologies, Inc. 1-760-431-8284	Carlsbad is releasing acyclovir tablets as they become available.
Aztreonam for Injection	BMS 1-800-332-2056	
7/1/2010	Baxter 1-888-229-0001	Baxter has frozen aztreonam 1 gram (NDC 00003-2230-11) and 2 gram (NDC 00003-2240-11) presentations.
	APP 1-888-386-1300	Aztreonam for Injection, USP is now available from APP in the following presentations: 1gm vial 63323-401-20 2gm vial 63323-402-20 The product is now available through wholesalers or APP.
Calcium Disodium Versenate Injection 200 mg/mL 5 mL ampules (NDC 29336-400-10)	Graceway Pharmaceuticals, 1-484-321-5600	Product is now available with a new NDC #29336-400-10.
10/28/2009		
Dexrazoxane for Injection, Zinecard	Pfizer- Zinecard: 1-800-533-4535	Zinecard now available from Pfizer. See Dear Health Care Provider Letter (PDF - 39KB)[1]
10/26/2009	Ben Venue- Dexrazoxane (generic): 1-800-562-4797	Totect available, labeled for use in treatment of extravasation resulting from IV anthracycline chemotherapy. TopoTarget inquiries:

		1-866-470-8247
		Dexrazoxane (generic)- product remains unavailable from Ben Venue due to manufacturing delays
Elspar	Lundbeck 1-847-282-1000	Lundbeck has released new production.
6/22/2010		
Erythromycin Ophthalmic Ointment	Bausch and Lomb Customer Service Number 1-800-323-0000	Bausch & Lomb is currently releasing erythromycin ophthalmic ointment as it becomes available.
2/25/2010		
	Fera Pharmaceutical, LLC (414) 434-6604	Fera Pharmaceuticals has available Erythromycin Ophthalmic Ointment USP, 1g x 50, NDC#48102-008-11, 3.5 g tube in 24 count cartons as well as the single 3.5 g tube.
Gemfibrozil Tablets	Pfizer 1-800-533-4535	Pfizer has available Lopid 600 mg tablets in 60 (NDC 00071-0737-20) and 500 (NDC 00071-0737-30) count presentations.
6/22/2010		
	Camber Pharmaceuticals 1- 866-495-1995	Camber has gemfibrozil available in 60 count (NDC 31722-0225-60) and 500 count (NDC 31722-0225-05) sizes.
	Teva Pharmaceuticals 1-800-545-8800	Teva has gemfibrozil 600 mg tablets in 60 count and 500 count presentations on allocation.
Indomethacin for injection	Bedford Customer Service 1-440-232-3320	Bedford now has Indomethacin injection in 1mg vials available (NDC 55390-299-01) and this product is being released to wholesalers.
updated 2/24/2010		
		Indocin IV is currently not available from Lundbeck.
	Lundbeck Inc. Customer Service 1-888-514-5204	
Intron A (interferon alfa-2b, recombinant) for Injection	Merck Customer Service Number: 1-800-222-7579	Merck has the INTRON A Powder for Injection and Solution for Injection in Vials in good supply.
7/2/2010		
Methotrexate injection	Bedford Laboratories Customer Service 1-800-562-4797	Methotrexate injection is available in multiple presentations and no further shortages are anticipated. For specific information regarding available strengths/sizes, please contact the manufacturers.
3/16/2010		
	Bioniche Pharma 1-888-258-4199	
	Ebewe Parenta Pharmaceuticals, Inc. 1-800-898-9948	
	Hospira Customer Service 1-877-946-7747	
	APP Pharmaceuticals Customer Service 1-888-386-1300	
Morphine Sulfate Oral Solution 100mg per 5ml (20mg/ml), 20mg/5ml and 10mg/5ml updated 1/27/2010	Roxane Laboratories Customer Service (1-800 520-1631)	Roxane Laboratories has recently received FDA approval for Morphine Sulfate Oral solution 100mg per 5ml (20 mg/ml). This is the only FDA approved morphine sulfate oral solution available at this concentration. The firm has sufficient supply to meet the entire market demand and no shortage is anticipated. Morphine 20mg/5ml and 10mg/5ml remain available as approved products as well. For the morphine 100mg per 5ml (20mg/ml), there will be a transition period to the new packaging, labeling, and NDC numbers. In the meantime, please continue to use the following NDC numbers: NDC 0054-0352-44 Morphine Sulfate Oral Solution CII, 20mg/mL 30mL Bottle. NDC 0054-0352-50 Morphine Sulfate Oral Solution CII, 20mg/mL

Nimbex (cisatracurium) injection	Abbott Laboratories 1-800-255-5162	120mL Bottle. Abbott reports availability of all presentations.
7/8/2010		
Nitrostat sublingual tablets (0.3 mg, 0.4 mg, and 0.6 mg)	Pfizer Inc.	Pfizer has sufficient inventory and is able to meet market demand.
updated 4/13/2010		Dear Healthcare Provider Letter (PDF - 451KB)[2]
Octreoscan (Kit for the Preparation of Indium In 111 Pentetreotide)	Covidien Product Monitoring and Drug Safety 1-800-778-7898	Please see Dear Valued Customer Letter (PDF - 25KB)[3]
2/12/2010		
Pre-pen (benzyl penicilloyl-polylysine) injection	Pre-Pen is being manufactured by Allerquest and distributed by ALK-Abello (1-800-325-7354)	Pre-Pen has been reintroduced to the market and is now available.
12/08/2009		
Tamiflu (oseltamivir phosphate) powder, for oral suspension, 12mg/ml	Roche	For more information see: Tamiflu Oral Suspension Shortage Information[4]
2/5/2010		
Tikosyn (500mcg and 250mcg capsules)	Pfizer Inc.	Please see Dear Healthcare Professional Letter (PDF - 29KB)[5] for additional information
1/15/2010		

Links on this page:

1. http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM187867.pdf
2. http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM208504.pdf
3. http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM200293.pdf
4. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm188236.htm
5. http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM197766.pdf